IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Application No. 10/511,888	*Confirmation No. 4210*
Filed:	October 19, 2004	
Applicants:	Dirk Cremer et al.	This Declaration was electronically filed on_____, 2008 using the USPTO's EFS-Web.
Title:	MATRIX COMPRISING A BIOACTIVE COMPONENT CONTAINING PHOSPHOLIPID	
Art Unit:	1618	
Examiner:	Blessing M. Fubara	
Attorney Docket:	5942/83518	
Customer No.:	22242	

DECLARATION of Dirk Cremer

I, Dirk Cremer , declare as follows:

1. I am the inventor of the above entitled patent application.

2. My education includes PhD studies and a doctoral thesis at the University of Muenster, Germany (PhD thesis/graduation finished in April 1999) and a Postdoctoral Position at the Ohio State University (August 1999 – July 2000).

3. I have been directly involved in the development in nutraceutical/ pharmaceutical compositions which effect health benefits. In my employment and my position as an R&D Manager between 2001 and 2005, I did the following work in developing nutraceutical/pharmaceutical compositions:

- Stable formulations of lecithin and phospholipids such as phosphatidylserine for encapsulation into soft gelatine capsules and other galenic forms
- Apply microencapsulation technologies such as spray-cooling, fluidized bed coating, coacervation, complex coacervation, liposome/micelle technology to substances such as lecithins, phosphatidylserine and alpha-lipoic acid in order to obtain formulations of increased stability and better functionality in finished product applications.

4. The compositions described in the instant above identified patent application include a matrix with a bioactive component which includes phosphatidyl serine and phosphatidyl choline. As described in the specification of the instant application identified above, because these materials act as emulsifiers, the encapsulation of phospholipids often causes problems such as the capsules becoming permeable in short times. This causes the capsules to leak. The matrix described in the instant application is extremely stable, is solid or highly viscous, and additionally has tailor made rheological properties, i.e. shows sheer thinning and behaves nearly like a pseudoplastic liquid. These properties of the matrix are tailor made and in particular achieved by the presence of waxy components.

5. I have read WO 01/84961 (Kiliaan). Kiliaan, such as in Example 1, describes a capsule which includes as active components phosphatidyl serine, phosphatidyl choline, omega fatty acids, and vitamins. The latter blend, however, as judged from the composition as such is unlikely to have the ingredients in an amount and ratio that would make any whole matrix solid or paste-like at room temperature or make the blend highly viscous and have the same tailor made rheological properties to provide the stability described in the

6. Kiliaan el al. do not describe a stable solid matrix. Because the amounts and relative amounts of phosphatidyl serine, other fatty (PUFA fatty acids, Vitamin E) and waxy components (no addition of waxes) are significantly different from what is described in the above instant application, based upon my experience, the capsule described in Kiliaan's Example 1 would not be a dosage form which becomes a solid matrix at room temperature, nor would it have the shear thinning properties as described in the above instant application.

7. Further, by virtue of my experience in formulating materials with phospholipids, due to the amounts of fatty substances other than phospholipids and the absence of waxy components in Kiliaan's Example 1, a stable matrix would not be formed. As a result, Kiliaan's blend of ingredients and relative amounts of ingredients would not provide the properties and stability described and sought in the instant above identified application. Also, Kiliaan's composition of Example 1 contains a mixture of herbal extracts which would not promote stability of any matrix in Killiaan's blend per se.

8. It also is my understanding there has been a question raised about how a person of ordinary skill in the technology described in the instant application would understand the phrases "derivatives of tocopherols" and "derivatives of tocotrienols." Vitamin E is a collective name for eight naturally occurring compounds: the chemical compounds α-tocopherol, β-tocopherol, γ-tocopherol and δ-tocopherol and α-tocotrienol, β-tocotrienol, γ-tocotrienol and δ-tocotrienol. In chemistry, a derivative is a compound that is formed from a similar compound if an atom is replaced with another atom or group of atoms. As can be seen from textbooks on vitamins, derivatives of the above mentioned vitamin E homologues also are well known. The derivatives tocopherol acetate and tocopherol succinate are the most common and usual dosage forms for the

application of vitamin E. Hence, in my experience in the technology of the instant application, a person of ordinary skill would understand the phrases "derivatives of tocopherols" and "derivatives of tocotrienols."

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon, hereby decares that the above statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

Date: Dec-01-2008 Dirk Cremer

Dirk Cremer

Date: Dec-11-2008 Elisabeth Markl

Elisabeth Markl